

# Exhibit 21

*United States of America ex rel. Ven-A-Care of the Florida Keys, Inc.,  
et al. v. Dey, Inc., et al.*, Civil Action No. 05-11084-PBS

**Exhibit to the Declaration of Marisa A. Lorenzo in Support of Dey's  
Motion to Exclude the Opinions of Mark Duggan, Ph.D.**

February 5, 2010

Renée Brooker  
Assistant Director  
U.S. Department of Justice  
Civil Division-Fraud Section  
610 D Street, NW  
Suite 9918  
Washington, DC 20530

Re: United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Abbott  
Laboratories, MDL 1456  
United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Dey, Inc. et al.,  
MDL 1456  
and  
United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Boehringer  
Ingelheim Corp., et al., MDL 1456.

Dear Ms. Brooker,

Abbott Confidence Intervals

1. My June 19, 2008 Abbott report and the January 23, 2009 supplemental report included a typographical error in the final row of Table 27B, which was the total of all values for 19 states. Specifically, the Excel sum formula inadvertently omitted the data for Nevada, which was the first state listed in this table. The corrected version of Table 27B is attached to this document. This also affects the totals in Table 25, and thus a corrected version of this table is attached to this document as well.

2. Per the court's request, the following summarizes the calculations of the 90 and 95 percent confidence intervals for the total value of federal DIFFERENCE. In my initial report, I estimated this for the 38 states for which I did not use state claims data as follows.

$$(1) \quad FED\_DIFFERENCE_{38} = \sum_{s=1}^{38} \sum_{n=1}^{44} \sum_{t=1}^{44} \bar{d}_{nt} F_{snt}$$

3. In this equation,  $\bar{d}_{nt}$  is equal to the average DIFF\_FRAC for product  $n$  in quarter  $t$  in the states (up to 10) for which I used state-produced claims data.  $F_{snt}$  is equal to federal spending in state  $s$ , on product  $n$ , in quarter  $t$ , calculated using SMRF/MAX or SDU data multiplied by the federal Medicaid assistance percentage in effect for that state in that quarter.

4. With 38 states, 44 products, and 44 quarters, there are potentially 73,568 different values of  $F_{snt}$ . Because not all state-product-quarter combinations have claims, the actual number is 34,434. Additionally, for 425 of these there is no  $\bar{d}_{nt}$  because none of the 10 states have a DIFF\_FRAC, and thus the number of  $F_{snt}$  values considered is 34,009.

5. The variance of the sum in equation 1 can be written as follows.

$$(2) \quad \text{var} \left\{ \sum_{s=1}^{38} \sum_{n=1}^{44} \sum_{t=1}^{44} \bar{d}_{nt} F_{snt} \right\}$$

6. Each value of  $\bar{d}_{nt}$  is calculated as follows.

$$(3) \quad \bar{d}_{nt} = \frac{1}{10} (d_{39,n,t} + \dots + d_{48,n,t})$$

7. The subscripts  $s = 39$  through 48 correspond to the 10 states for which I used state-produced claims data. In many instances, the number of states is less than 10, in which case equation 3 is revised to reflect this.

8. The value of  $d_{snt}$  varies across states, products and quarters and is calculated using a large number of claims in each state. If one assumes that these variables,  $d_{snt}$ , are uncorrelated and that they have the same standard deviation,  $\sigma_{nt}$ , then the variance of the average of these values can be calculated as follows.

$$(4) \quad \text{var}(\bar{d}_{nt}) = \frac{1}{10} \text{var}(d_{nt})$$

9. To account for the possibility that the values of  $d_{nt}$  vary systematically across states, one can introduce a state-specific shift factor,  $\mu_s$ , that allows each state to differ systematically from the average,  $\bar{d}_{nt}$ .

10. With these assumptions one can estimate the variation of diff as follows.

$$(5) \quad \text{var} = \left( \sum_{s=1}^{38} F_{snt} \right)^2 \text{var}(\bar{d}_{nt}) + \left( \sum_{n=1}^{44} \sum_{t=1}^{44} F_{snt} \right)^2 \text{var}(\mu_s)$$

$$(6) \quad \text{var} = F_{nt}^2 \text{var}(\bar{d}_{nt}) + F_s^2 \text{var}(\mu_s)$$

11. To estimate this variance, one can calculate the sample standard deviation for each  $d_{nt}$  using the 10 states. To increase the precision of this estimate one can use observations for all state  $d_{snt}$  values within a year (thus considering up to 40 observations to estimate the sample  $\sigma_{nt}$ ), though the results are similar if calculated quarterly.

12. To estimate  $\text{var}(\mu_s)$ , one can begin by fitting a regression of the following type based on the 10 states.

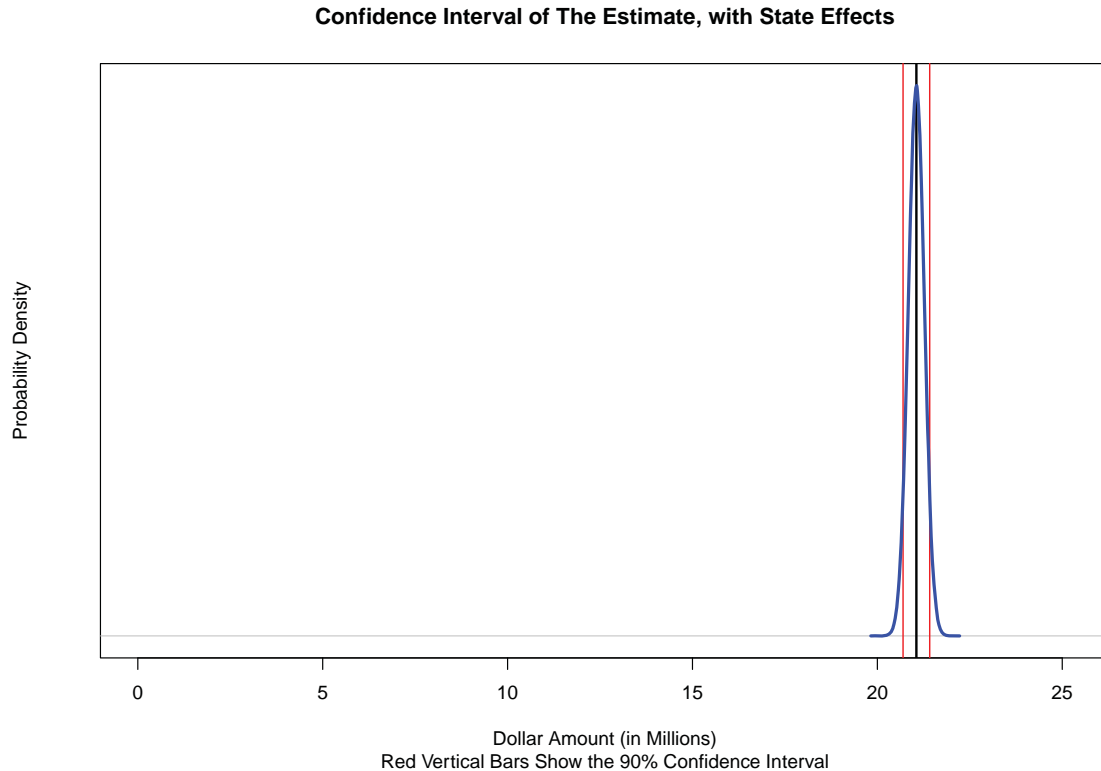
$$(7) \quad d_{snt} = \sum_{n=1}^{44} \sum_{t=1}^{44} \beta_{nt} I_{nt} + \sum_{s=1}^{10} \mu_s I_s + \varepsilon_{snt}$$

13. In equation 7,  $I$  is an indicator variable. In the first pair of sums, each of these 1,775 variables takes on the value 1 if the product and quarter considered are  $n$  and  $t$ . In the second sum, each of the 10 variables takes on the value 1 if the state is  $s$ .

14. The estimated variance of  $\mu_s$  from this regression sheds light on whether and to what extent states in the sample differ systematically from one another. The  $R^2$  of the regression with just the  $I_{nt}$  terms is 0.6435 whereas adding the state indicators,  $I_s$ , increases this to 0.6737. Eight of the state-effect regression coefficients are statistically significant at the 95% level, indicating that there is systematic variation across states. The standard deviation of these 10 state effects is 0.0402426, including a value of 0 for the state omitted from the regression.

15. Using this, one can then calculate 90 and 95 percent confidence intervals for the total value of difference in the 38 states. The point estimate for the difference is \$21.055 million

and the standard deviation of the estimate is \$0.218 million. Thus the 90% confidence interval ( $1.65\sigma$ ) is [\$20.695 million, \$21.416 million] and the 95% confidence interval ( $1.96\sigma$ ) is [\$20.627 million, \$21.483 million]. Stated another way, with 90% probability the true federal difference is between \$20.695 million and \$21.416 million, and with 95% probability it is between \$20.627 million and \$21.483 million. The 90 percent confidence interval is depicted graphically below.



**Figure 1. Abbott 90% Confidence Interval.**

16. Even if one were to double the variance of  $\mu$  to account for the possibility that  $\text{var}(\mu_s)$  is larger for the 38 states than the 10, the standard deviation increases to just \$0.287 million. Thus, the 90% confidence interval would change to [\$20.582 million, \$21.527 million].

17. It is instructive to compare this estimate with the federal differences calculated when using state claims data for 9 additional states when state-produced data was provided to me. In that case, the point estimate of the difference is \$4.106 million and the value obtained using claims data is \$4.030 million, with a difference from the extrapolation of \$0.077 million. The standard deviation of the estimate is approximately \$0.067 million, less than 1.15 standard deviations from the point estimate.

18. Additionally, one can calculate confidence intervals of the extrapolation from the 10 states to the remaining 29 states. In this case, the estimate is \$14.662 million, the standard deviation is \$0.190 million, the 90 percent confidence interval is [\$14.349 million, \$14.975 million], and the 95 percent confidence interval is [\$14.290 million, \$15.035 million].

#### Dey Confidence Intervals

19. In my Dey report of January 23, 2009, I performed a similar extrapolation to the one I performed for Abbott. Using an analogous approach to that described above, one can calculate 90 and 95 percent confidence intervals for the total value of difference in the 34 states in the Dey extrapolation. The point estimate for the difference is \$59.412 million and the standard

deviation of the estimate is \$2.508 million. Thus the 90% confidence interval ( $1.65\sigma$ ) is [\$55.274 million, \$63.550 million] and the 95% confidence interval ( $1.96\sigma$ ) is [\$54.497 million, \$64.328 million]. Stated another way, with 90% probability the true federal difference is between \$55.274 million and \$63.550 million, and with 95% probability it is between \$54.497 million and \$64.328 million. The 90 percent confidence interval is depicted graphically in Figure 2, attached.

20. It is instructive to compare this estimate with the federal differences calculated when using state claims data for 16 additional states when state-produced data was provided to me. In that case, the point estimate of the difference is \$18.244 million and the value obtained using claims data is \$17.043 million, with a difference from the extrapolation of \$1.201 million. The standard deviation of the estimate is approximately \$1.146 million, less than 1.05 standard deviations from the point estimate.

#### Roxane Confidence Intervals

21. In my Roxane report of February 9, 2009, I again performed a similar extrapolation to those I performed for Abbott and Dey. Using an analogous approach to that described above, one can calculate 90 and 95 percent confidence intervals for the total value of difference in the 33 states in the Roxane extrapolation. The point estimate for the difference is \$20.304 million and the standard deviation of the estimate is \$0.703 million. Thus the 90% confidence interval ( $1.65\sigma$ ) is [\$19.144 million, \$21.463 million] and the 95% confidence interval ( $1.96\sigma$ ) is [\$18.927 million, \$21.681 million]. Stated another way, with 90% probability the true federal difference is between \$19.144 million and \$21.463 million, and with 95% probability it is between \$18.927 million and \$21.681 million. The 90 percent confidence interval is depicted graphically in Figure 3, attached.

22. It is instructive to compare this estimate with the federal differences calculated when using state claims data for 9 additional states when state-produced data was provided to me. In that case, the point estimate of the difference is \$4.686 million and the value obtained using claims data is \$4.690 million, with a difference from the extrapolation of \$0.004 million. The standard deviation of the estimate is approximately \$0.303 million, less than 0.014 standard deviations from the point estimate.

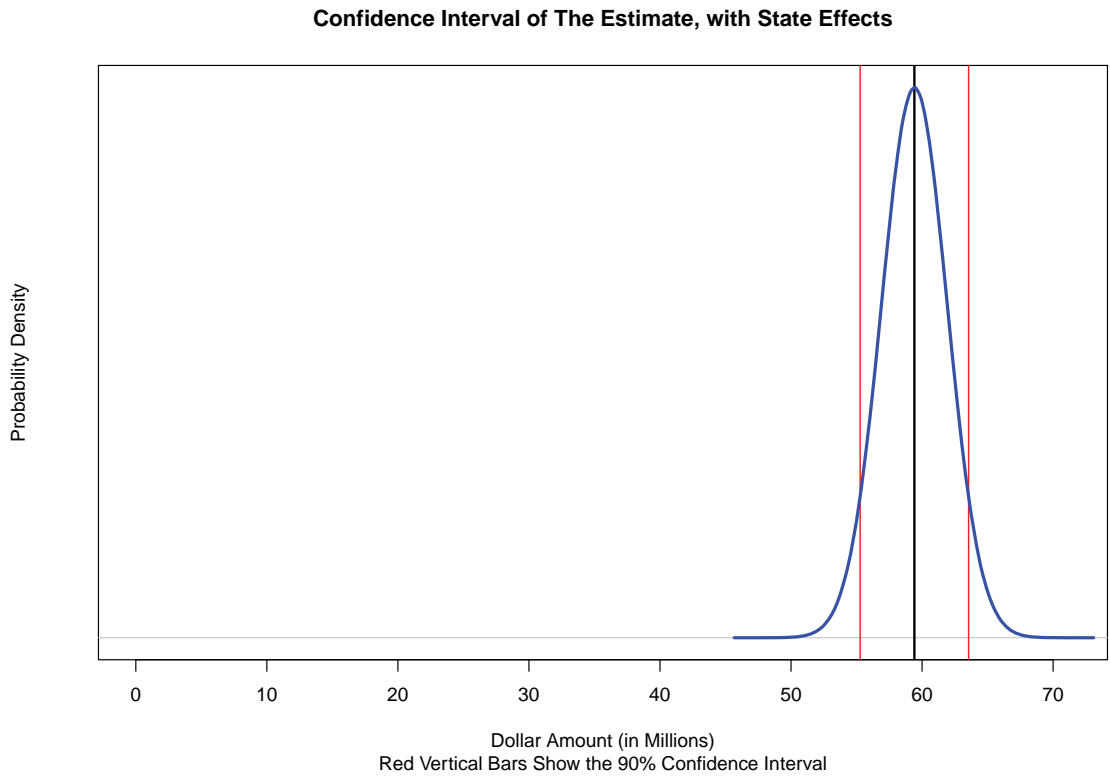
#### Summary

23. These confidence interval calculations provide further support for the appropriateness of the methodology I used in my Abbott, Dey and Roxane reports. Moreover, it goes beyond what much related peer-reviewed research has done when estimating similar outcome variables of interest. For example, in the *Journal of Health Economics* paper by Gruber and Rodriguez, that I discussed extensively at the court hearing, in which the authors used data from a non-random sample of physicians to estimate uncompensated care provided by all physicians in the U.S., no similar confidence intervals are calculated.

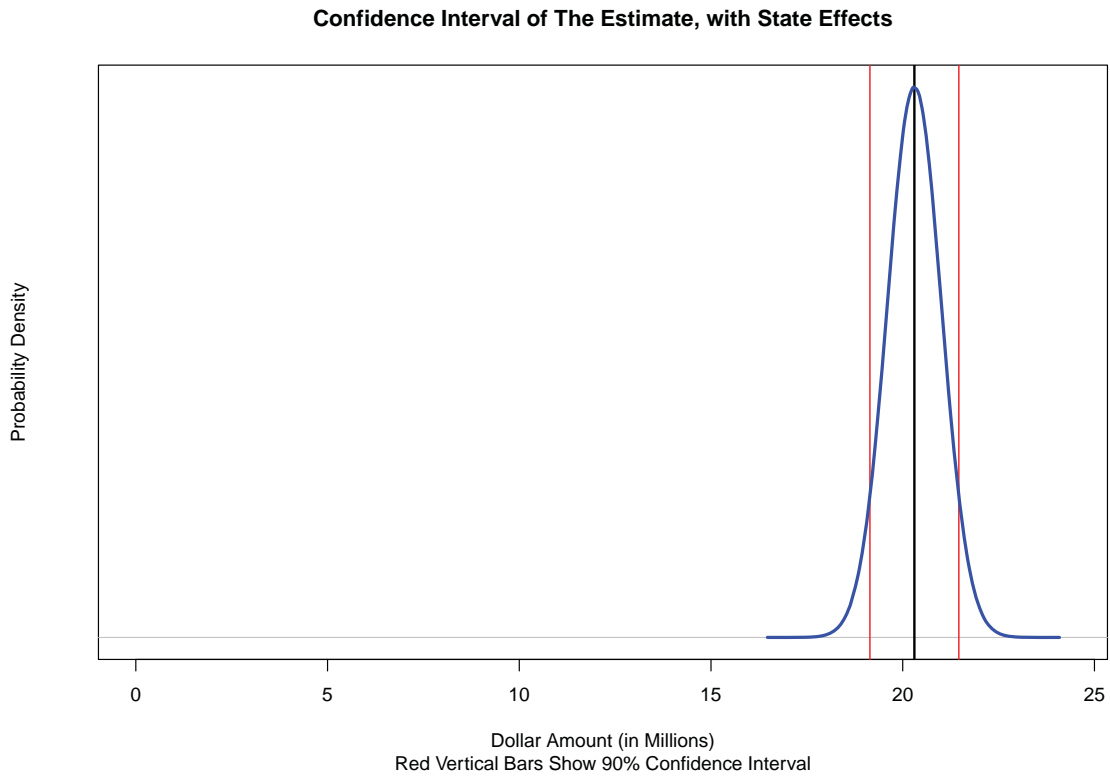
Sincerely,



Mark G. Duggan, Ph.D.



**Figure 2. Dey 90% Confidence Interval.**



**Figure 3. Roxane 90% Confidence Interval.**

**Table 25: Medicaid Summary for Top Nine States, Louisiana (#11), and Wisconsin (#16)**

State	Source	Time Period	# Clms w/DIFF>0	# Claims	Aggregate DIFF	Total MCD Paid	Federal DIFF	# Pharm. Payments
Illinois	State Claims	1991Q2-2001Q4	519,450	534,183	\$12,029,039	\$16,527,505	\$6,014,519	58,631
Florida	State Claims	1993Q4-2001Q4	278,623	287,959	\$11,700,280	\$15,561,037	\$6,532,311	67,076
Florida	SDUD Data	1991Q1-1993Q3	34,802	39,861	\$939,551	\$1,379,301	\$514,820	-
California	State Claims	1994Q2-2001Q4	267,167	280,994	\$7,044,315	\$9,172,917	\$3,585,421	56,269
New Jersey	State Claims	1992Q1-2001Q4	124,513	126,067	\$7,191,020	\$8,453,921	\$3,595,511	11,446
New Jersey	SDUD	1991Q1-1991Q4	12,374	13,798	\$727,856	\$915,392	\$363,928	-
New York	State Claims	1993Q1-2001Q4	108,386	120,315	\$6,877,666	\$8,921,858	\$3,438,833	38,184
New York	SDUD	1991Q1-1992Q4	5,263	5,791	\$149,690	\$192,898	\$74,845	-
Indiana	SMRF / MAX	1992Q1-2001Q4	175,577	182,042	\$11,214,412	\$14,812,193	\$6,936,732	28,880
Indiana	SDUD	1991Q1-1991Q4	8,572	9,044	\$137,297	\$249,529	\$86,826	-
Kentucky	State Claims	1995Q1-2001Q4	96,452	100,007	\$4,737,344	\$6,190,786	\$3,331,076	16,044
Kentucky	SMRF / MAX	1992Q1-1994Q4	17,559	20,725	\$545,830	\$910,013	\$390,572	3,589
Kentucky	SDUD	1991Q1-1991Q4	2,961	3,401	\$77,795	\$128,833	\$56,759	-
Missouri	State Claims	1998Q1-2001Q4	70,680	75,389	\$3,448,247	\$4,263,226	\$2,087,491	8,304
Missouri	SMRF / MAX	1992Q1-1997Q4	54,763	66,684	\$2,070,637	\$3,184,492	\$1,246,043	8,024
Missouri	SDUD	1991Q1-1991Q4	1,568	2,136	\$35,736	\$63,533	\$21,377	-
Michigan	State Claims	2000Q4-2001Q4	14,389	15,986	\$537,789	\$792,346	\$300,440	4,479
Michigan	SMRF / MAX	1994Q1-2000Q3	66,339	81,215	\$2,551,829	\$4,222,782	\$1,393,735	14,000
Michigan	SDUD	1991Q1-1993Q4	6,844	9,722	\$66,162	\$157,114	\$36,565	-
Louisiana	State Claims	1995Q1-2001Q4	73,705	76,520	\$2,970,914	\$3,834,631	\$2,102,350	7,211
Louisiana	SDUD	1991Q1-1994Q4	8,417	9,408	\$257,830	\$407,099	\$190,429	-
Wisconsin	State Claims	1993Q2-2001Q4	63,647	70,145	\$1,683,017	\$2,440,008	\$998,395	13,988
Wisconsin	SDUD	1991Q1-1993Q1	2,976	3,248	\$73,335	\$105,891	\$44,110	-
Total for First 11 States		1991-2001	2,015,027	2,134,640	\$77,067,591	\$102,887,305	\$43,343,090	336,125
Total for Remaining 38 States			851,097	900,501	\$34,433,402	\$48,451,768	\$21,055,294	148,081
<b>Total for All 49 States</b>			<b>2,866,124</b>	<b>3,035,141</b>	<b>\$111,500,993</b>	<b>\$151,339,073</b>	<b>\$64,398,384</b>	<b>484,206</b>

**Table 27B: Medicaid Summary for States 31 through 49**

State	Source	Time Period	# Clms w/DIFF>0	# Claims	Aggregate DIFF	Total MCD Paid	Federal DIFF	# Pharm. Payments
Nevada	SMRF / MAX	1999-2001	3,151	3,333	\$313,653	\$422,338	\$156,916	711
Nevada	SDUD	1991-1998	2,413	2,601	\$230,364	\$327,451	\$115,912	
Nebraska	SMRF / MAX	1999-2001	6,286	6,629	\$183,483	\$273,719	\$112,073	2,250
Nebraska	SDUD	1991-1998	12,779	13,484	\$349,284	\$484,720	\$212,924	
Kansas	SMRF / MAX	1992-2001	24,239	25,749	\$539,427	\$826,369	\$319,822	5,416
Kansas	SDUD	1991	521	733	\$3,784	\$10,510	\$2,170	
Iowa	SMRF / MAX	1992-2001	21,315	22,714	\$748,339	\$1,061,276	\$473,722	8,249
Iowa	SDUD	1991	682	864	\$20,242	\$32,121	\$12,835	
South Dakota	SMRF / MAX	1999-2001	3,523	3,716	\$121,249	\$173,158	\$82,919	1,018
South Dakota	SDUD	1991-1998	7,492	7,816	\$199,782	\$269,774	\$134,959	
Rhode Island	SMRF / MAX	1995, 1999-01	3,320	3,544	\$146,362	\$224,157	\$79,411	548
Rhode Island	SDUD	1991-94, 1996-98	2,921	3,054	\$162,159	\$205,523	\$86,912	
Montana	SMRF / MAX	1992-2001	6,811	7,204	\$232,208	\$327,431	\$164,312	1,914
Montana	SDUD	1991	128	171	\$4,709	\$7,883	\$3,378	
Hawaii	SMRF / MAX	1999-01, 1992-93	4,676	5,003	\$42,857	\$72,730	\$21,989	451
Hawaii	SDUD	1991, 1994-98	5,074	5,527	\$141,798	\$198,849	\$70,989	
Maine	SMRF / MAX	1992-2001	5,101	5,419	\$257,479	\$364,368	\$167,290	2,437
Maine	SDUD	1991	48	81	\$1,659	\$3,021	\$1,054	
Wyoming	SMRF / MAX	1992-2001	5,010	5,235	\$256,674	\$360,392	\$162,206	1,873
Wyoming	SDUD	1991	12	21	\$350	\$615	\$239	
Tennessee	SDUD	1991-1994	863	918	\$81,949	\$116,412	\$55,695	
Delaware	SMRF / MAX	1993-2001	5,962	6,381	\$206,399	\$305,021	\$103,282	1,299
Delaware	SDUD	1991-1992	171	221	\$4,375	\$8,418	\$2,189	
North Dakota	SMRF / MAX	1992-2001	3,174	3,362	\$147,621	\$222,881	\$103,241	1,925
North Dakota	SDUD	1991	82	95	\$1,359	\$2,628	\$951	
Idaho	SMRF / MAX	1996-2001	176	180	\$20,409	\$27,036	\$14,085	184
Idaho	SDUD	1991-1995	80	85	\$25,988	\$38,046	\$18,538	
New Hampshire	SMRF / MAX	1992-2001	3,424	3,607	\$74,806	\$112,152	\$37,403	1,496
New Hampshire	SDUD	1991	47	89	\$760	\$2,151	\$380	
New Mexico	SMRF / MAX	1996-2001	554	590	\$20,076	\$27,284	\$14,615	559
New Mexico	SDUD	1991-1995	415	453	\$4,812	\$7,921	\$3,548	
Alaska	SMRF / MAX	1992-2001	2,280	2,456	\$37,159	\$59,789	\$19,485	578
Alaska	SDUD	1991	26	38	\$302	\$765	\$151	
Vermont	SMRF / MAX	1992-2001	1,683	1,797	\$42,645	\$63,732	\$26,400	422
Vermont	SDUD	1991	157	192	\$1,806	\$4,702	\$1,119	
Washington, D.C.	SMRF / MAX	1999-2001	436	458	\$15,415	\$23,509	\$7,708	246
Washington, D.C.	SDUD	1991-1998	962	994	\$18,654	\$25,640	\$9,327	
Total		1991-2001	135,994	144,814	\$4,660,397	\$6,694,492	\$2,800,149	31,576